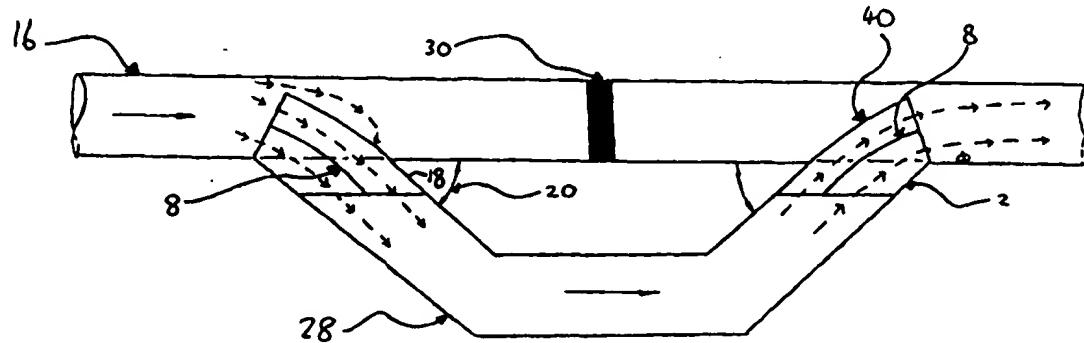


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## (54) Title: HAEMODYNAMIC CONTROL DEVICE



## (57) Abstract

The present invention provides a graft haemodynamic control device suitable for reducing anastomotic intimal hyperplasia, comprising a cylindrical body, optionally with control vanes therein, which connects an artery to a bypass graft and which controls the flow of blood therebetween. The device is made of any compliant material, usually a plastic material such as PTFE, Dacron or Goretex and coated with Teflon. The device is less compliant than the graft. It may be attached to the artery and the graft by recognised techniques.

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1        "Haemodynamic Control Device"

2

3        The invention relates to the surgical procedure of  
4        using biological or synthetic grafts to bypass occluded  
5        or severely stenosed arteries. Intimal hyperplasia in  
6        the vicinity of the vascular anastomoses is a primary  
7        factor in the medium and long-term failure of grafts.  
8        This invention is a haemodynamic control device which  
9        judiciously adapts the local flow field, by reducing  
10       both the spatial shear stress gradients and the extent  
11       of long particle residence times in the vicinity of an  
12       anastomosis, thereby reducing the likelihood of intimal  
13       hyperplasia and the subsequent failure of the graft.

14

15       In this field it is already known that

16

17       1.       Anastomotic intimal hyperplasia is a common cause  
18       of post-operative vascular graft failure,  
19       especially for synthetic grafts.

20

21       2.       In addition to graft/artery compliance mismatch  
22       the other primary mechanism which is universally  
23       acknowledged to promote intimal hyperplasia is  
24       adverse haemodynamic flow patterns in the vicinity  
25       of the anastomosis.

1       3. The most common regions exhibiting intimal  
2       hyperplasia are around the suture line, at the  
3       heel and toe of the anastomosis and along the  
4       floor opposite the anastomosis (see Figure 3).  
5

6       4. Development of intimal hyperplasia is more  
7       prevalent at the distal anastomosis than at the  
8       proximal anastomosis.  
9

10      5. There is a direct relationship between the  
11       localities of intimal hyperplasia and the  
12       anastomotic surface which are experiencing low  
13       shear and long particle residence times.  
14

15      6. High spatial wall shear stress gradients promote  
16       intimal hyperplasia.  
17

18      7. The anastomotic graft angle is of fundamental  
19       importance to defining the wall shear stress: a  
20       shallow or small anastomotic angle results in a  
21       decreased region of separated flow which reduces  
22       the likelihood of intimal hyperplasia.  
23

24      8. The anastomotic angle is limited both by the graft  
25       material and the mechanics of suturing/skill of  
26       the surgeon.  
27

28      The types of vascular patients that the surgeons treat  
29       fall principally into three groups:  
30

31      **Group 1 - Normal Vascular Patients:**  
32

33-     Typically these patients have atherosclerosis, viz a  
34       disease process affecting the wall of arteries and in  
35       this group it involves the main arteries of the tummy  
36       and thigh extending to about knee level. Essentially

1 this is a process in which yellow fatty plaques build  
2 up eccentrically in the arterial wall in different  
3 locations. This proceeds at a rate depending on  
4 certain critical stimuli, to cause occlusion of the  
5 artery. As the plaque develops a varying degree of  
6 calcium forms in it causing a varying degree of  
7 hardness producing a softish thick walled artery to an  
8 artery which will not accept a needle.

9

10 The plaque undergoes a degree of necrosis and blood  
11 then clots on it causing complete occlusion, this is a  
12 thrombus and it propagates proximally i.e. upstream to  
13 the next main branch of the vessel where it stops. The  
14 vessels of the calf are only ever mildly affected.

15

16 **Group 2 - The Diabetic Vascular Patient:**

17

18 This patient often has a degree of disease distribution  
19 as described above though usually the thigh artery is  
20 affected. However this group has the disease always in  
21 the three vessels of the calf, the tibial arteries and  
22 they are in parallel. They may be hard but principally  
23 have concentric layers of atheroma building to cause  
24 skip like areas of narrowing and occlusion. Even these  
25 are amenable to bypass. But in the diabetic the real  
26 problem are the arterioles, the tiny little vessels  
27 that bleed when you cut yourself shaving. These are  
28 narrowed by the building up of hyaline, a tough scar  
29 like material. Again the arterioles are considered to  
30 be in parallel hence further increase in peripheral  
31 resistance.

32

33 **Group 3 - The Renal Vascular Patient:**

34

35 The kidney patient relies frequently on dialysis and is  
36 often Diabetic. This group tends to have a very poor

1      prognosis for in addition to the common features of the  
2      Group's 1 and 2 their vessels are remarkably hard even  
3      early in life. On the other hand the wall may be very  
4      soft but mushy and thick. Their prognosis is  
5      determined too by the state of the arterioles and as  
6      yet unrecognised biochemical abnormalities relating to  
7      the primary renal pathology.

8

9      There is also an interesting but relatively rare group  
10     of patients who suffer from thrombophilia which is  
11     essentially the opposite of haemophilia where the  
12     patient has a disorder of the haemopoietic system in  
13     which there is a tendency for thrombosis to occur.

14

15     Currently all present research into this field appears  
16     to be cited around optimising the graft material and  
17     not controlling the flow at the anastomoses.

18

19     However, this has the disadvantage that, without  
20     haemodynamic control at the distal, and to a lesser  
21     extent at the proximal anastomosis one will always  
22     incur high spatial shear stress gradients in the  
23     vicinity of the anastomotic junction and therefore  
24     intimal hyperplasia.

25

26     In the medium to long-term, the graft will eventually  
27     fail, thus necessitating a new surgical bypass  
28     procedure with all the additional risks which it  
29     entails.

30

31     According to the present invention there is provided a  
32     graft haemodynamic control device suitable for reducing  
33     anastomotic intimal hyperplasia, the device comprising  
34     a substantially cylindrical body wherein one end is  
35     capable of being attached to a bypass graft and the  
36     other end capable of being positioned in an artery such

1 that the device connects the graft and the artery and  
2 controls the flow of blood there between.

3

4 The device may be manufactured from the same compliant  
5 material as the graft but will be less compliant.

6

7 The device may be of one piece construction.

8

9 The device may be manufactured in a variety of sizes  
10 and options to match the chosen graft/host artery's  
11 architecture.

12

13 In one embodiment the device is configured to be a  
14 proximal control device controlling flow from an artery  
15 to a graft.

16

17 In an alternative embodiment the device is configured  
18 to be a distal control device to control flow of blood  
19 from graft into artery.

20

21 The invention may further comprise a kit including  
22 proximal and distal haemodynamic control devices.

23

24 In one embodiment the device comprises at least one  
25 control vane such that flow is directed between the  
26 artery and graft to decrease spatial shear stress  
27 gradients and long particle residence times in the  
28 vicinity of anastomoses.

29

30 More preferably the device comprises at least one  
31 control valve such that flow is directed between the  
32 artery and graft to decrease spatial shear stress  
33 gradients when used in larger diameter host arteries.  
34 Larger diameter host arteries are defined as having a  
35 bore of greater than 6 mm.

36

1 In one embodiment the control vane divides the body of  
2 the device into two separate chambers.

3

4 Suitably the device may be manufactured from any  
5 compliant material.

6

7 Preferably the device is coated with teflon or a  
8 similar material.

9

10 Preferably also the device is manufactured from any one  
11 or any mixture of the group consisting of PTFE, Dacron  
12 or Goretex.

13

14 Suitably the device may be attached to grafts using  
15 established methodology such as suturing or biological  
16 glues.

17

18 The shape and dimensions of the device will differ  
19 depending on the size of the host artery and graft and  
20 on whether it is to be attached at the proximal or  
21 distal ends of the graft.

22

23 In a preferred embodiment the device comprises a  
24 peripheral collector, which may comprise a thin  
25 compliant porous area, to enhance flow vectoring into  
26 the graft.

27

28 The invention can further comprise a peripheral  
29 ejector, which may comprise a thin compliant porous  
30 area, in the device to enhance flow vectoring into the  
31 host artery.

32

33 Suitably the device can further comprise secondary  
34 control vanes to enhance flow vectoring into and out of  
35 larger diameter grafts.

36

1 Most preferably the device can further comprise  
2 secondary control vanes to enhance flow vectoring into  
3 and out of larger diameter grafts (diameters greater  
4 than 1 cm).

5

6 The diameter of the device according to the invention  
7 can range from 2mm to 1.5cm depending on the size of  
8 the grafts and the host arteries being connected.

9

10 Typically a device according to the present invention  
11 is of a synthetic one-piece construction and  
12 incorporates a primary control vane and a periphery  
13 collector or ejector.

14

15 The device may include constant angle guidelines to  
16 assist attachment to the graft at optimum anastomotic  
17 angle.

18

19 The invention further provides a kit comprising a  
20 synthetic graft and proximal and distal haemodynamic  
21 control devices.

22

23 Suitably one end is unattached to allow the other end  
24 to be cut to size.

25

26 The invention also provides preattached or integral  
27 haemodynamic control devices on synthetic grafts.

28

29 The present invention will now be further described by  
30 way of example with reference to the accompanying  
31 drawings, in which:

32

33 Figure 1 is a front view of the haemodynamic flow  
34 control device, taken along a cross section, showing a  
35 schematic enlargement of a haemodynamic control device  
36 for proximal side-to-end anastomosis.

1      Figure 2 is a front view of the haemodynamic flow  
2      control device of Fig. 1, taken along a cross section,  
3      showing the schematic haemodynamic flow pattern for an  
4      occluded bypass graft with the haemodynamic flow  
5      control device of the present invention fitted at both  
6      the proximal and distal anastomoses;

7

8      Figure 3 shows the schematic haemodynamic flow pattern  
9      for an occluded bypass graft with regions of intimal  
10     hyperplasia in the vicinity of the distal end-to-side  
11     anastomosis;

12

13     The haemodynamic flow control device as shown in  
14     Figures 1 and 2 is formed from a single piece of  
15     plastic material 2, which is shaped to form a  
16     cylindrical body 4. The bore 6 of cylindrical body 4  
17     is divided into two by control vane 8 and is further  
18     divided into four by parallel secondary control vanes  
19     10 and 12. Control vanes 8, 10 and 12 run along the  
20     longitudinal axis of cylindrical body 4. The rim 14 of  
21     cylindrical body 4, designed to be sutured into the  
22     host artery 16 has an overlap flap 18 running the  
23     outside of the cylindrical body 4 at anastomotic angle  
24     20 from one edge of the rim 14. The area of the  
25     cylindrical body 4, above the overlap flap 18 is  
26     porous. Also running around the edge of the  
27     cylindrical body 4 at the end designed to be attached  
28     to the graft and at the anastomotic angle 20, are a  
29     series of incisions 22, 24 and 26 spaced equidistantly,  
30     as graft attachment guidelines (synthetic grafts only).

31

32     In use the haemodynamic flow device (2) is attached to  
33     host artery 16 at anastomotic angle 20 by virtue of  
34     overlap flap 18, by conventional methods and is  
35     attached to graft 28 in order to bypass occlusion 30.  
36     Use of the flow control device helps to prevent effects

1 shown in figure 3 such as undesirable flow effects 32  
2 and 34 and helps to prevent intimal hyperplasia build  
3 ups 36, 38 and 40.

4

5 This invention is a novel vascular graft haemodynamic  
6 control device (HCD) which can be attached at either,  
7 or both, the proximal and distal anastomotic junctions.  
8 The HCD judiciously adapts the local flow field, by  
9 decreasing both the spatial shear stress gradients and  
10 the extent of long particle residence times in the  
11 vicinity of an anastomosis, thereby reducing the  
12 likelihood of intimal hyperplasia and the subsequent  
13 long-term failure of the graft.

14

#### 15 HCD Design

16

17 The HCD is of a synthetic one-piece construction and  
18 can optionally incorporate a primary control vane (8)  
19 with optional secondary control vanes (10,12) and an  
20 optional periphery collector/ejector. Fig 2 shows a  
21 typical vascular bypass graft with two HCD's attached  
22 at both the proximal and distal anastomoses. Both of  
23 the HCD's depicted in Fig 2 contain a primary control  
24 vane and the optional periphery collector/ejector. The  
25 HCD is manufactured in a variety of sizes and options  
26 to match the chosen graft/host arteries' architecture.

27

#### 28 Primary Control Vane

29

30 The primary control vane (8) (see Fig 1) is a thin  
31 compliant haemodynamic flow vectoring control surface.  
32 The length, axial location and variable pitch of the  
33 primary control vane is optimised for the HCD size,  
34 locality (i.e. proximal or distal) and the elasticity  
35 of the host artery.

36

## 1      Optional Secondary Control Vanes

2

3      The optional secondary control vanes (10,12) (see Fig  
4      1) are thin compliant haemodynamic flow control  
5      surfaces which are utilised to enhance flow vectoring  
6      into and out of the larger diameter grafts. The  
7      length, axial location and variable pitch of these  
8      control vanes are once again optimised for the HCD  
9      size, locality (i.e. proximal or distal) and elasticity  
10     of the host artery.

11

## 12     Optional Periphery Collector/Ejector

13

14     The optional periphery collector/ejector (40) (see Fig  
15     2) is a thin compliant porous haemodynamic collector or  
16     ejector device depending on whether the HCD is at the  
17     proximal or distal anastomosis respectively. The  
18     length, porosity and variable pitch of the periphery  
19     collector/ejector is dependant on the primary control  
20     vane dimensions, the locality (i.e. proximal or distal)  
21     and elasticity of the host artery. The periphery  
22     collector/ejector is utilised to enhance flow vectoring  
23     and to reduce the extent of long particle residence  
24     times fore and aft of the occlusion.

25

## 26     Surgical HCD Attachment Procedure

27

28     The HCD may be attached (during the surgical procedure)  
29     to existing synthetic or biological grafts using a  
30     variety of established methodologies, including  
31     suturing and biological glues. The HCD is attached to  
32     the graft in a manner which allows a small overlap of  
33     graft material to remain above the attachment point  
34     thereby enabling the surgeon to suture and/or bond the  
35     graft onto the artery as normal (see Fig 2). As  
36     depicted in Fig 2 the HCD synthetic graft attachment

1 procedure can be made more straightforward by the  
2 addition of constant angle guide-lines (22,24,26) along  
3 the length of the graft thus ensuring that the surgeon  
4 attaches the graft and HCD at the optimum anastomotic  
5 angle. (Note: pre-attached (or integral) HCDs on the  
6 proximal end of synthetic grafts can be employed to  
7 simplify/expedite some of the more uncomplicated  
8 surgical bypass procedures).

9

10 The advantages of the invention and/or the ways in  
11 which the disadvantages of previously known  
12 arrangements are overcome, include:

13

14 Procedural:

15

16 1. The haemodynamic control device judiciously adapts  
17 both the proximal and distal anastomotic graft  
18 flow-patterns thereby reducing both local spatial  
19 shear stress gradients and the extent of long  
20 particle residence times thus decreasing the  
21 likelihood of intimal hyperplasia in the  
22 vicinities of the heel, toe and floor regions  
23 (see Fig 3).

24

25 2. The associated increase in the medium to long-term  
26 patency of the graft anastomoses enhances the  
27 patient's survival rate.

28

29 3. The graft/control device attachment procedure is  
30 relatively straightforward and the associated  
31 synthetic graft suturing guide-lines ensure that  
32 the surgeon attaches the graft at the optimum  
33 anastomotic angle.

34

35 4. The control device may also be utilised in  
36 biological grafts.

1      Fiscal:

2

3      1.   The control device can be attached to existing  
4                    grafts.

5

6      2.   Enhanced medium to long-term patency reduces the  
7                    need to perform expensive staff intensive re-  
8                    operative procedures which are statistically less  
9                    successful than the original procedure.

10

11

1      **Claims**

2

3      1. A haemodynamic control device suitable for  
4      reducing anastomotic intimal hyperplasia, the  
5      device comprising a substantially cylindrical body  
6      wherein one end is capable of being attached to a  
7      bypass graft and the other end capable of being  
8      positioned in an artery such that the device  
9      connects the graft on the artery and controls the  
10     flow of blood there between.

11

12     2. A haemodynamic control device as claimed in Claim  
13     1, which is configured to be a proximal control  
14     device controlling flow from an artery to a graft.

15

16     3. A haemodynamic control device as claimed in Claims  
17     1 or 2 which is configured to be a distal control  
18     device to control flow of blood from graft into  
19     artery.

20

21     4. A haemodynamic control device as claimed in Claims  
22     1, 2 or 3, which comprises a least one  
23     longitudinal control vane.

24

25     5. A haemodynamic control device as claimed in Claim  
26     4 wherein the control vane divides the body of the  
27     device into two separate chambers.

28

29     6. A haemodynamic control device as claimed in any  
30     preceding Claim which is manufactured from a  
31     compliant material.

32

33     7. A graft haemodynamic control device as claimed in  
34     Claim 6 wherein the compliant material is less  
35     compliant than the material of the graft.

36

- 1 8. A haemodynamic control device as claimed in any  
2 preceding Claim, which is manufactured from any  
3 one or any mixture of the group consisting of  
4 PTFE, Dacron or Goretex.
- 5
- 6 9. A haemodynamic control device as claimed in any  
7 preceding Claim which is coated with a Teflon type  
8 material.
- 9
- 10 10. A haemodynamic control device as claimed in any  
11 preceding Claim, which is attachable to grafts  
12 using established methodology such as suturing or  
13 biological glues.
- 14
- 15 11. A haemodynamic control device as claimed in any of  
16 Claims 1, 2 and 4 to 10 comprising a peripheral  
17 collector, which may comprise a thin compliant  
18 porous area, to enhance flow vectoring into the  
19 graft.
- 20
- 21 12. A haemodynamic control device as claimed in any of  
22 Claims 1 and 3 to 10 which further comprises a  
23 peripherally ejector, which may comprise a thin  
24 compliant porous area, in the device to enhance  
25 flow vectoring into the host artery.
- 26
- 27 13. A haemodynamic control device as claimed in any  
28 preceding Claim which further comprises secondary  
29 control vanes to enhance flow vectoring into or  
30 out of an outer large diameter graft.
- 31
- 32 14. A kit comprising at least one proximal  
33 haemodynamic control device and at least one  
34 distal haemodynamic control device.
- 35
- 36 15. A synthetic graft including a haemodynamic control

- 1 device as claimed in any of the preceding Claims.
- 2
- 3

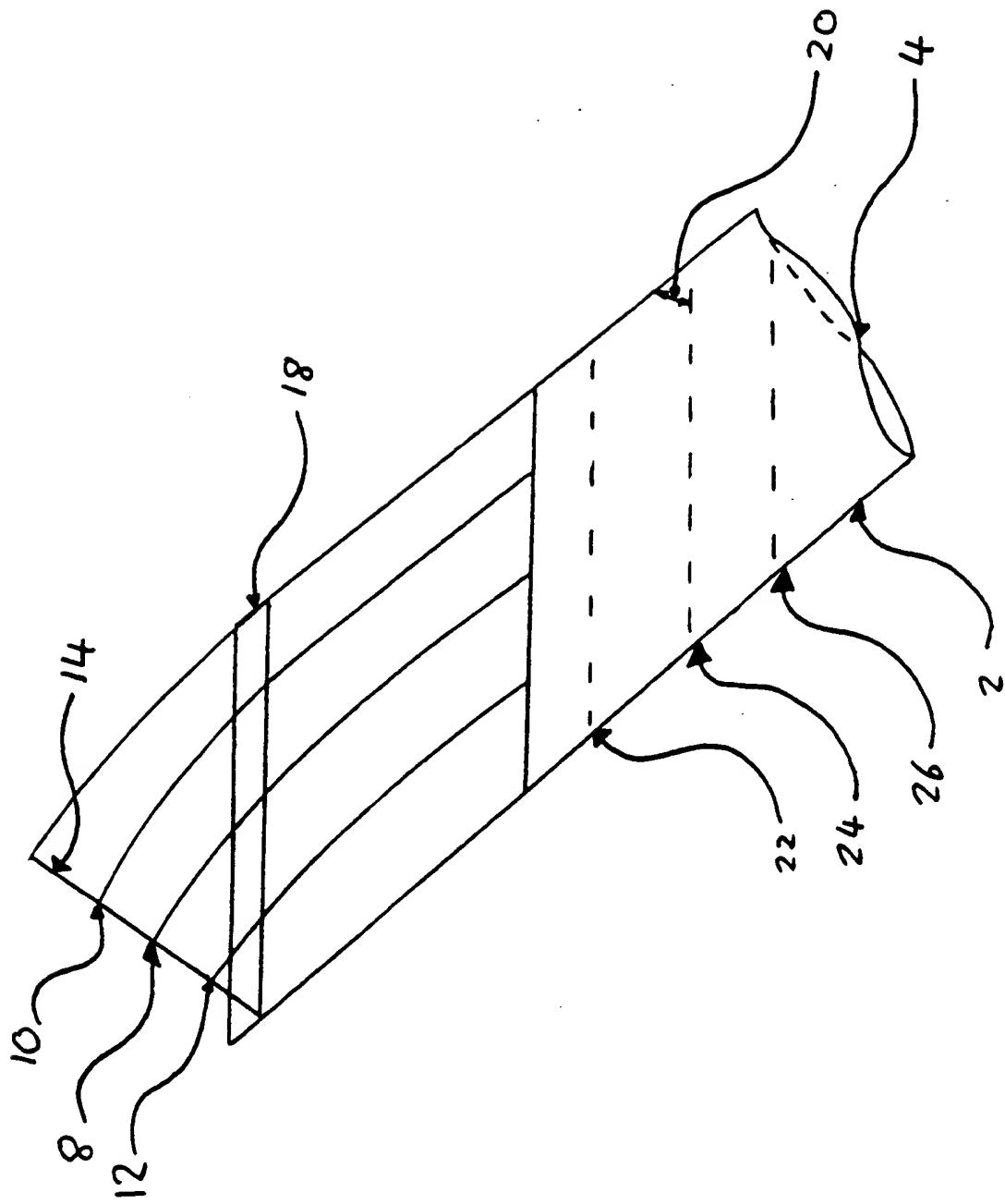


Figure 1  
1/3

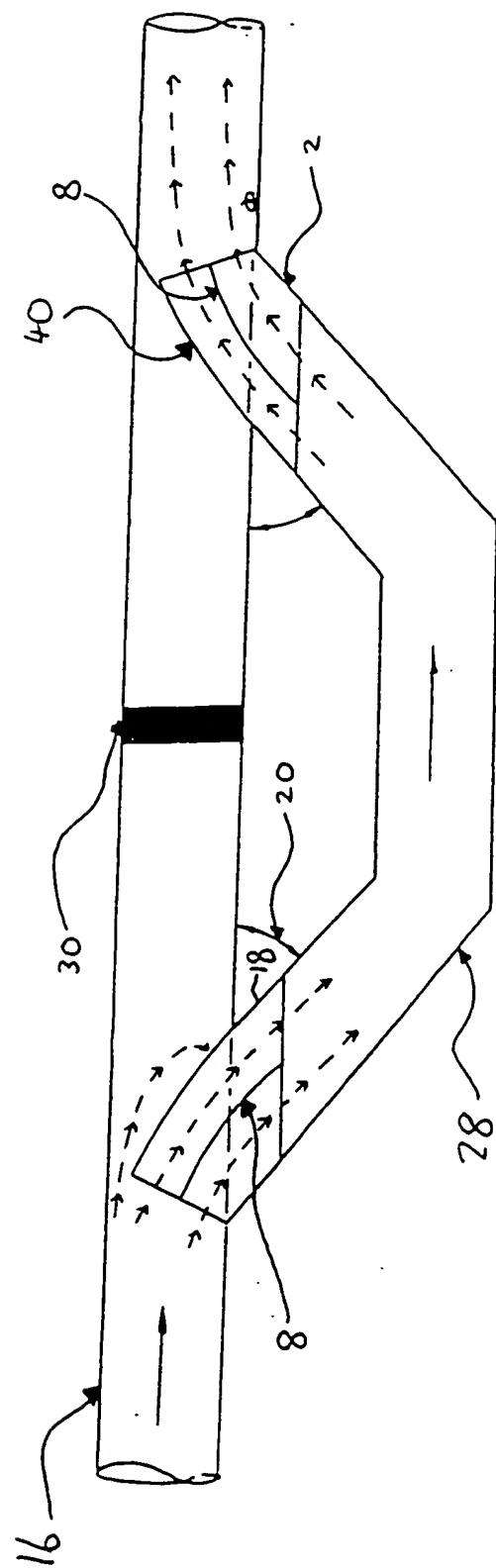


Figure 2  
2/3

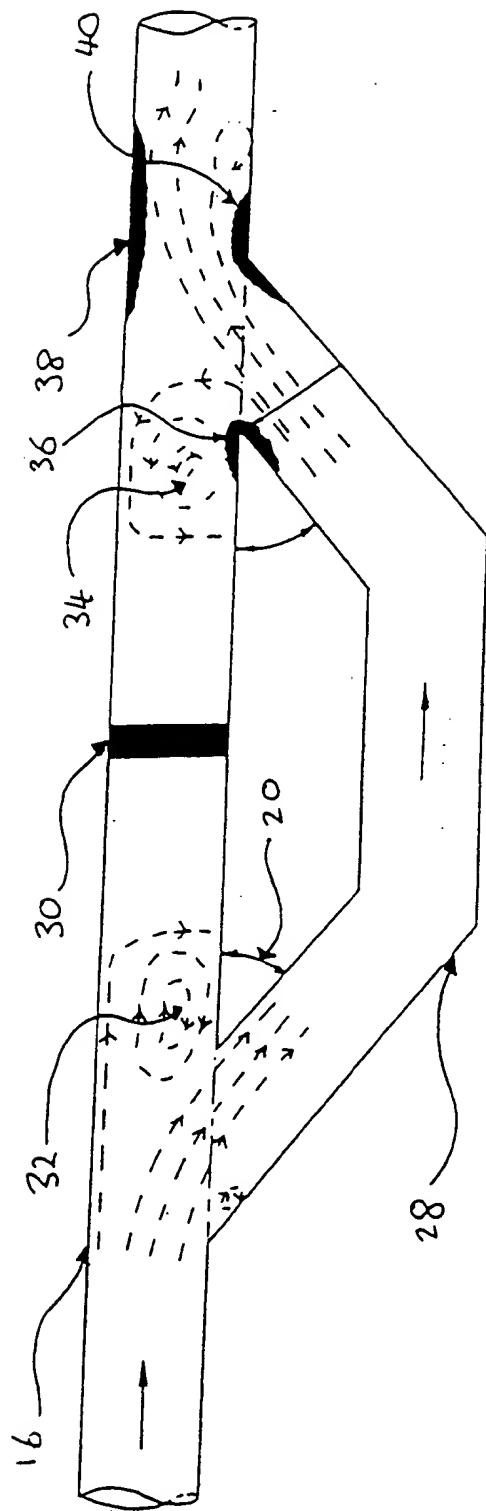


Figure 3  
3/3

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 6 A61F2/06 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 6 A61F A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 503 568 A (MADRAS) 12 March 1985 see the whole document ---	1,14,15
A	US 3 882 862 A (BEREND) 13 May 1975 ---	
A	US 3 818 511 A (GOLDBERG ET AL) 25 June 1974 -----	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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## Information on patent family members

International Application No

PCT/GB 98/01006

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4503568	A 12-03-1985	NONE	
US 3882862	A 13-05-1975	NONE	
US 3818511	A 25-06-1974	NONE	